

## **REMARKS**

Claims 39-40 have been cancelled with this amendment. No new matter is added. Applicant respectfully requests the entry of the amendments and reconsideration of the application in view of the amendments and the following remarks.

### **Finality of Office Action**

Applicants respectfully request reconsideration of the finality of the Office Action of June 23, 2009. A new ground of rejection is presented in the Office Action of June 23, 2009. The Office Action states that the new ground of rejection was necessitated by the amendment of March 6, 2009 in which claim 35 was amended to change the scope and breadth of the claim and claims 41 and 42 were amended. However, the amendment of March 6, 2009 merely incorporated limitations from claims 41 and 42 into the base claim (claim 35). All of the limitations were before the Examiner previously so that the amendment should not have necessitated a new ground of rejection. Reconsideration and withdrawal of the finality of the Office Action of June 23, 2009 is respectfully requested.

### **Rejection under 35 U.S.C. § 103(a)**

Claims 35-37, 39-40, and 43 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Merck (DE 3405663; machine translation and partial translation by Applicant submitted March 6, 2009) in view of Weissbach (Journal of Organic Chemistry 23: 329-330, 1958) in view of Mopper (Analytical Biochemistry 87: 162-168, 1978) and in view of the Encyclopedia Britannica, entry for separation and purification relied upon to show common knowledge in the art). Kiely, et al. (Annals of the New York Academy of Sciences 165 (2): 559-563, 1969) is cited to provide evidence of known inherent chemical properties. SIGMA-Aldrich (Technical Information Bulletin AL-142) is provided as evidence of the composition of Amberlite MB-3 resin.

The method steps taught by Merck for obtaining scyllo-inositol are very different from the method steps of Applicants' claims. Merck isolated scyllo-inositol from the reaction mixture obtained by reducing esterified myo inosose with sodium borohydride by removing boric acid

with azeotropy. Merck does **not** disclose the formation of a scyllo-inositol/boric acid complex by adding boric acid and a metal salt.

The Examiner considers that borate is generated *in situ* by the addition of sodium borohydride which is equivalent to the addition of boric acid, but one of ordinary skill in the art would not expect that scyllo-inositol/boric acid is formed during this procedure because of the presence of methanol in the reduction reaction performed in the method of Merck. Methanol is added to separate off the borate (see translation of page 2, paragraph 12 provided by Applicants with response March 6, 2009).

Furthermore, Merck does not disclose the addition of metal salt selected from the group consisting of "NaCl, NaHCO<sub>3</sub>, Na<sub>2</sub>CO<sub>3</sub>, Na<sub>2</sub>SO<sub>4</sub>, NaHSO<sub>4</sub>, NaH<sub>2</sub>PO<sub>4</sub>, Na<sub>2</sub>HPO<sub>4</sub>, Na<sub>3</sub>PO<sub>4</sub>, borax, KCl, KHCO<sub>3</sub>, K<sub>2</sub>CO<sub>3</sub>, K<sub>2</sub>SO<sub>4</sub>, KHSO<sub>4</sub>, KH<sub>2</sub>PO<sub>4</sub>, K<sub>2</sub>HPO<sub>4</sub>, K<sub>3</sub>PO<sub>4</sub>, MgCl<sub>2</sub>, MgCO<sub>3</sub>, and MgSO<sub>4</sub>" as claimed. Merck neither discloses the formation of scyllo-inositol/boric acid complex, nor the separation of the complex. The Examiner's assertion that "Merck discloses the procedure is known to produce borate from sodium borohydride (page 2, paragraph 12 provided by Applicant) Merck discloses acidifying the borohydride reduction product with 2N hydrochloric acid (page 2, paragraph 12 provided by Applicant), treating the complex of boron and scyllo-inositol with acid" (Office Action, page 4, last paragraph) is in error. Nowhere in the translation of page 2, paragraph 12 of Merck provided by Applicants (or in the machine translation) does Merck teach or suggest either the formation of a scyllo-inositol/boric acid complex or its separation.

Merck also fails to disclose the fourth step as recited in Applicants' claim 35 because Merck adds methanol to remove boric acid with azeotropy. Merck does not precipitate scyllo-inositol as in the present invention. The amount of methanol added in Merck is 10 times the volume of the reaction mixture which is quite different from the claimed method in which "the methanol is added in a volume 0.3 to 5 times the volume of the acidic solution or acidic suspension" (claim 35). One of ordinary skill in the art would not arrive at the volume of methanol as claimed from Merck because the purpose of adding methanol in Merck (azeotropy) is totally different from the purpose of adding methanol in the claimed invention (precipitation).

Weissbach disclose the formation of the scyllo-inositol/boric acid complex and isolation of the complex as a precipitate. However, Weissbach does not disclose addition of a metal salt selected from the group consisting of "NaCl, NaHCO<sub>3</sub>, Na<sub>2</sub>CO<sub>3</sub>, Na<sub>2</sub>SO<sub>4</sub>, NaHSO<sub>4</sub>, NaH<sub>2</sub>PO<sub>4</sub>,

Na<sub>2</sub>HPO<sub>4</sub>, Na<sub>3</sub>PO<sub>4</sub>, borax, KCl, KHCO<sub>3</sub>, K<sub>2</sub>CO<sub>3</sub>, K<sub>2</sub>SO<sub>4</sub>, KHSO<sub>4</sub>, KH<sub>2</sub>PO<sub>4</sub>, K<sub>2</sub>HPO<sub>4</sub>, K<sub>3</sub>PO<sub>4</sub>, MgCl<sub>2</sub>, MgCO<sub>3</sub>, and MgSO<sub>4</sub>” as claimed. Neither Merck nor Weissbach teach this feature. The present invention is distinguished from the teaching of Weissbach (and Merck) in that the scyllo-inositol/boric acid complex in the present invention is efficiently formed by adding metal salts together with the boric acid which is neither taught nor suggested by Weissbach (or Merck). Weissbach also fails to teach precipitation with methanol or ethanol. Accordingly, the references taken together as a whole do not teach the claimed invention.

The Examiner refers to the Encyclopedia Britannica to support the statement in the Office Action that “ion exchange and absorption chromatography are known for the same purpose of as [sic] precipitation and crystallization as a separations method based on liquid-solid phase equilibria” (Office Action, page 6, 2<sup>nd</sup> full paragraph). This is not correct. These separation methods are not alternative to each other because ion exchange chromatography is a separation method based on the equilibrium of the reaction of a compound with an ion exchangeable functional group of the column while precipitation is a separation method based on the liquid-solid equilibrium. Therefore, one of ordinary skill in the art would never have been motivated to combine Merck with Weissbach.

Mopper discloses the formation of sugar-borate complex in solution and separation using ion-exchange chromatography. However, as discussed above, ion-exchange chromatography is a separate method from crystallization. Accordingly, one of ordinary skill in the art would not apply the teaching of Mopper on buffer pH and salinity in ion exchange chromatography to a precipitation reaction.

Moreover, Mopper does not even teach the limitations of claim 35. Mopper does not disclose that scyllo-inositol/boric acid complex is precipitated by “adding boric acid and a metal salt into a liquid mixture containing scyllo-inositol and neutral sugar other than scyllo-inositol in an amount by mol two times or more that of scyllo-inositol dissolved in the liquid mixture” (claim 35). Mopper discloses that sugars generally interact weakly with borate to form a complex in solution, whereas the present invention teaches that scyllo-inositol specifically interacts strongly with borate in the presence of a metal salt to form a precipitate. The disclosure of Mopper on properties of sugar-borate complexes does not pertain to the precipitation of

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scyllo-inositol in the Weissbach document so that one of ordinary skill in the art would never think to combine these two documents.

Kiely merely teaches that the diborate of scyllo-inositol precipitates which is already known from Weissbach.

Accordingly, the cited references taken as a whole do not teach or suggest the claimed invention.

In view of Applicants' arguments, reconsideration and withdrawal of the rejection is respectfully requested.

#### **No Disclaimers or Disavowals**

Although the present communication may include alterations to the application or claims, or characterizations of claim scope or referenced art, Applicant is not conceding in this application that previously pending claims are not patentable over the cited references. Rather, any alterations or characterizations are being made to facilitate expeditious prosecution of this application. Applicant reserves the right to pursue at a later date any previously pending or other broader or narrower claims that capture any subject matter supported by the present disclosure, including subject matter found to be specifically disclaimed herein or by any prior prosecution. Accordingly, reviewers of this or any parent, child or related prosecution history shall not reasonably infer that Applicant has made any disclaimers or disavowals of any subject matter supported by the present application.

#### **CONCLUSION**

In view of Applicants' amendments to the claims and the foregoing Remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number appearing below.

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Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

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